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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,279	07/08/2003	Richard Harkins	51791AUSD1	4679
27586	7590	07/05/2005	EXAMINER	
BERLEX BIOSCIENCES PATENT DEPARTMENT 2600 HILLTOP DRIVE P.O. BOX 4099 RICHMOND, CA 94804-0099			SZPERKA, MICHAEL EDWARD	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/616,279

Applicant(s)

HARKINS ET AL.

Examiner

Michael Szperka

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-29, 31-41 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) 24-29, 31-34, 36-41, and 44-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/8/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Claims 24-29, 31-41 and 44-46 are pending in the instant case.

Applicant's election of Group II, claim 35, drawn to method of destroying a cell that expresses the polypeptide of SEQ ID NO:2, and the species election of the peptide epitope of SEQ ID NO:10 in the reply filed on April 29, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 24-29, 31-34, 36-41 and 44-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made **without** traverse in the reply filed on April 29, 2005 as explained above.

2. Applicant is reminded to update the status of all applications referenced in the specification. Specifically, Applicant is asked to update the first line of the specification to indicate that application 09/732,357 is now US Patent 6,682,902.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

3. Applicant's affidavit dated July 8, 2003 indicating that inventor Renate Steinbrecher has changed her name to Renate Parry due to marriage is acknowledged. However, this affidavit is not the appropriate way in which to convey such information to the office. To change the name of the inventor after the application has been filed, a petition under 37 CFR 1.182 must be filed. See MPEP 605.04(c).

The oath/declaration in the instant application has been carried over from parent application 09/732,357, which indicates Renate Steinbrecher as an inventor. Since the instant application is a divisional of 09/732,357, and the marriage occurred after the filing of 09/732,357, a petition is required to change the name of Renate Steinbrecher to Renate Parry.

### ***Claim Objections***

4. Claim 35 is objected to because it refers to limitations found in a claim drawn to a non-elected invention. Applicant is invited to amend claim 35 to incorporate the limitations found in withdrawn claim 31.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Sheppard (WO 98/45442, of record as reference 03 on the IDS received August 8, 2005, see entire document) as evidenced by Kreitman (Exp. Op. Pharmacother, 2000, 1:1117-1129, see entire document).

Sheppard teaches antibodies and antibody fragments that specifically bind zsig25 (see entire document, particularly the abstract and from line 1 of page 67 to line 29 of page 68). The peptide of SEQ ID NO:10 of the instant application is 100% conserved in the zsig25 sequence disclosed by Sheppard (see enclosed copy of the sequence search notes), and as such antibodies that bind zsig25 also bind a polypeptide that comprises SEQ ID NO:10 of the instant invention. The antibodies of Sheppard are to be used for tagging cells and are to be coupled to drugs, toxin, and radionuclides for *in vivo* diagnostic and therapeutic applications (see particularly page 71, lines 1-19). Cells that are tagged with toxin-labeled antibodies would necessarily be selectively destroyed (Kreitman, see entire document, particularly the abstract).

Therefore, the prior art anticipates the claimed invention.

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claim 35 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 in light of claims 18-20 of copending Application No. 10/624,884. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are of overlapping scope. Specifically, claim 26 of 10/624,884 anticipates the instant invention in that the identity of the therapeutic agent coupled to the antibody is specifically recited in claim 20 of application 10/624,884.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claim 35 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 in light of claims 18-20 of copending Application No. 10/895,183. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are of overlapping scope. Specifically, claim 26 of 10/895,183 anticipates the instant

invention in that the identity of the therapeutic agent coupled to the antibody is specifically recited in claim 20 of application 10/895,183.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


10. No claim is allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 13, 2005

  
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